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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,564	11/21/2007	John R. Schreiber	000659-0057-101	6183

1473 7590 01/13/2010

ROPES & GRAY LLP
PATENT DOCKETING 39/361
1211 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-8704

EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
01/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,564	SCHREIBER, JOHN R.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Election 11/5/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *49,53,55,56,64 and 109* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,10,13,16-22,26,30,36,38-41,44-47,57-59,97,103-105,107 and 110-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 3,10,13,16-22,26,30,36,38-41,44-47,49,53,55-59,64,97,103-105,107 and 109-116.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 3, 10, 13, 16-22, 26, 30, 36, 38-41, 44-47, 57-59, 97, 103-105, 107 and 110-116 ***and*** an antibody that binds to the lipopolysaccharide (LPS) of *Pseudomonas aeruginosa* strain It-2 (011) and amino acid sequences SEQ ID NO: 13 and SEQ ID NO: 22, in the reply filed on 11/5/09 is acknowledged. Examination will be conducted with respect to antibodies that bind to *Pseudomonas aeruginosa* strain It-2. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3, 10, 13, 16-22, 26, 30, 36, 38-41, 44-47, 57-59, 97, 103-105, 107 and 110-116 encompass the elected invention.

Claims 49, 53, 55, 56, 64, 109 are withdrawn as being drawn to a non-elected invention.

Specification

2. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously

incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

See page 5, line 13, and page 13 paragraph [0051] of the instant specification which contain improper incorporation by reference.

Claim Rejections - 35 USC § 112-Deposit Requirements

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 103-105, 107, 110-112, 116, 3, 10, 13, 16-22, 26, 30, 36, 38-41, 44-47, 57-59 and 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the strain *P.aeruginosa* strain IT-2, the hybridoma cell lines which produce the claimed antibodies ***or*** the claimed antibodies. Because it is not clear that the properties of strain IT-2 or that the strain can be obtained from nature without undue experimentation, or that monoclonal antibodies which bind to its LPS-O specific polysaccharide are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of specific strain, a suitable deposit for patent purposes is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

© the deposits will be maintained in a public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a

period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become non-viable or non-replicable.

In addition, a deposit of the biological material that is capable of self-replication either directly or indirectly must be viable at the time of the deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1)The name and address of the depository;
2)The name and address of the depositor;
3)The date of deposit;
4)The identity of the deposit and the accession number given by the depository;
5)The date of the viability test;
6)The procedures used to obtain a sample if the test is not done by the depository; and
7)A statement that the deposit is capable of reproduction.

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

It is noted that the last page of the instant specification, page 39, recites:

BIOLOGICAL DEPOSITS

[0129] Hybridoma cell lines producing Mabs that recognize the LPS of strains Pa01, It-5, and It-6 were deposited in accordance with the provisions of the Budapest Treaty at the American Type Culture Collection (ATCC®), 10801 University Blvd., Manassas, VA 20110-2209, USA on August 6, 2003. They were assigned the following deposit designations and accession numbers:

aPa01 IgG2 Hybridoma PTA-5384

cflt-5 IgG2 Hybridoma PTA-5385

ait-6 IgG2 Hybridoma PTA-5386

However, hybridoma cell lines producing Mabs that recognize the LPS O-specific side chain of P.aeurginosa strain IT-2 are not listed as being deposited. A proper deposit of these hybridomas should be made.

Claim Rejections - 35 USC § 112-Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 103-105, 107, 110-112, 113-115 (part (a) only or part (b) only), 116, 3, 10, 13, 16-22, 26, 30, 36, 38-41, 44-47, and 57-59, 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are broadly drawn to any isolated human antibody or antigen-binding portion thereof which specifically binds LPS O-specific side chain of P.Aeruginosa It-2 (011). Monoclonal antibodies and hybridomas producing said monoclonals are also claimed, as are vaccines for preventing or inhibiting P.aeurognisa infection comprising said antibodies and methods of making said antibodies.

The instant claims do not recite a defined structure as neither the strain, nor the antibodies or cell line producing them have been deposited. The functional limitation of having the ability to bind to LPS O-specific side chain of P.Aeruginosa It-2 (011) does not adequately define the claimed structure so that one of skill in the art could make and/or use it. Only the isolated antibody which comprises a heavy comprising SEQ ID NO: 22 **and** a kappa light chain comprising an amino acid sequence comprising SEQ ID NO: 13 is enabled, absent a Deposit of a specific monoclonal antibody or cell line

producing said monoclonal antibody. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." A prior art literature search found no disclosure of strain It-2 or It-2(011) in the prior art. Accordingly, it is unclear how one of skill in the art would have the ability to identify and acquire said strain and produce specific antibodies against a LPS-O specific side chain.

The claims are also drawn to a passive vaccine and method for ***preventing*** *P.aeruginosa* infection in a population. The broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host. Prophylactic/preventative treatments e.g. vaccines for many infections do not prevent infection i.e. the entry of at least one microorganism but instead kill the organism once it infects tissues or cells thereby eliminating the infection or reducing microorganism burden, thus reducing or eliminating any disease caused by the infection. Such treatments do not prevent the organism from infecting in the first place. Prevention of

infection by a bacterium in general is a very high bar because the vaccine must prevent at least one bacterium from infecting a cell. Also, prevention of infection is different from prevention of disease caused by an infection as prevention of disease is prevention of symptoms due to an infection while preventing infection is inhibition of the infectious organism from invading or entering, for example, the human body, tissue, cells in the first place. The instant specification does not provide any evidence for prevention of an infection i.e. prevention of at least one single bacterium from infecting a patient. In the instant specification, antibodies produced by vaccination reduce incidence of bacteremia (blood stream infections) by opsonophagocytic activity/killing, but do not prevent/protect from infection. There is no evidence that administration of the claimed vaccines induced an effective host antibody response which was able to clear P.aeruginosa infection see page 28, paragraph [0090]. Thus, the vaccine cannot protect from infection, because vaccinated individuals still became infected. The specification has not given guidance on how to prevent/protect from infection caused by P.aerguinosa.

Claim Rejections - 35 USC § 112-Written Description

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 103-105, 107, 110-112, 113-115 (part (a) only or part (b) only), 116, 3, 10, 13, 16-22, 26, 30, 36, 38-41, 44-47, and 57-59, 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are broadly drawn to any isolated human antibody or antigen-binding portion thereof which specifically binds LPS O-specific side chain of P.Aeruginosa It-2 (011). Monoclonal antibodies and hybridomas producing said monoclonals are also claimed, as are vaccines for preventing or inhibiting P.aeurognisa infection comprising said antibodies and methods of making said antibodies. The instant claims do not recite a defined structure as neither the strain, nor the antibodies or cell line producing them have been deposited. Only the isolated antibody which comprises a heavy comprising SEQ ID NO: 22 **and** a kappa light chain comprising an amino acid sequence comprising SEQ ID NO: 13 has proper Written Description, absent a Deposit of a specific monoclonal antibody or cell line producing said monoclonal antibody.

In 1999, the United States Patent and Trademark Office ("USPTO") published training materials regarding the examination of patent applications under the written description requirement of 35 U.S.C. § 112, first paragraph. (See http ://www.uspto. gov/web/offices/pac/writtende sc.pdf). Since that time, the case law and technology have developed in such a way as to necessitate a revision of the 1999 training materials. Consequently, this 2008 revision was created to supersede and replace the 1999 training materials. To the extent that any conflict exists between the 1999 training materials and the present materials, the present materials

control. The claims have been evaluated with regard to written description based on the Written Description Guidelines and Training Materials published in 2008. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. Applicants have not described the genus of claimed antibodies such that the specification might reasonably convey to the skilled artisan that Applicants had possession of the claimed invention at the time the application was filed.

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601,

1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "'Written Description" Requirement (66 FR 1099-1111, January 5,2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed. The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus'" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be

achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al (Nature Biotechnology 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al, an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Chothia et al (THE EMBO JOURNAL, 1986, 5/4:823-26) also teach that there is a limit to how much substitution can be tolerated before the original tertiary structure is lost. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of fragments or variants of the eleven peptides, the skilled artisan could not immediately recognize that Applicants were in possession of the claimed genus of antibodies at the time of filing.

Therefore, because the art is unpredictable, in accordance with the Written Description Guidelines, the scope of the claim includes numerous structural variants (i.e. fragments), and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification does not describe any members of the claimed genus by complete structure. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative

number of species to describe the genus, and thus, that the applicant was not in possession of the claimed genus. The claimed subject matter is not supported by an adequate written description because a representative number of species has not been described. There are no drawings or structural formulas disclosed of any of these fragments or variants of the claimed polynucleotides, with the exception of an isolated antibody which comprises a heavy comprising SEQ ID NO: 22 and a kappa light chain comprising an amino acid sequence comprising SEQ ID NO: 13. Based on the lack of knowledge and predictability in the art, those of ordinary
skill in the art would not conclude that the applicant was in possession of the claimed genus of antibodies and fragments thereof based on disclosure of the single species of only the isolated antibody comprising a heavy chain consisting of the exact SEQ ID NOS: 22 and light chain consisting of the amino acid sequence of SEQ ID NO: 13 . A prior art literature search found no disclosure of strain It-2 or It-2(011) in the prior art. Accordingly, it is unclear how one of skill in the art would have the ability to identify and acquire said strain and produce specific antibodies against a LPS-O specific side chain. Written description is only provided for a single antibody that meets this description, e.g., an isolated antibody which comprises a heavy comprising SEQ ID NO: 22 and a kappa light chain comprising an amino acid sequence comprising SEQ ID NO: 13.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance

presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

1. Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to the Genus of antibodies 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). With regard to (4) the nature of the invention and (5) the state of the prior art, these have been discussed above. One of skill in the art would require guidance, in order to make or use the antibodies in the methods, kits and compositions as instantly claimed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 103-105, 116, 3, 10, 13, 16-21, 38-41, 44-47, and 57-59 are rejected under 35 U.S.C. 102(a) as being anticipated by Bedian et al (WO 03/040170 A2).

Bedian et al teach an isolated antibody which is 96.9% identical to Appliant's SEQ ID NO: 22 (Human anti-CD40 antibody 7-1-2 variable region light chain protein; seq id no:12) and an isolated antibody which has a sequence which is 89.4% identical

to Applicant's SEQ ID NO: 22 (Human anti-CD40 antibody 10-8-3 variable region heavy chain protein with 111 out of 120 identical matches). See sequence alignment available in Public PAIR under 'SCORE/SUPPL CONTENT' tab. These antibodies with such a high degree of homology would be expected to bind (have cross reactivity) to the same antigens as to those which are instantly claimed. The references teaches both polyclonal and monoclonal antibodies and hybridoma cell lines producing said monoclonal antibodies. Additionally, the reference teaches the use of antibodies as diagnostic reagents and kits comprising them. The term "vaccine" and "pharmaceutical composition" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of the antibodies. With respect to the product-by-process claims, e.g., claim 97, the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the

prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). Since Bedian et al teach antibodies with the same structure, eg., the antibodies would inherently possess at least one or more of the functional properties recited in claim 3.

11. Claims 103-105, 116, 3, 10, 13, 16-21, 38-41, 44-47, and 57-59 are rejected under 35 U.S.C. 102(a) as being anticipated by Gudas et al (WO 03/048328 A2).

Gudas et al teach an isolated antibody which is 87.8% identical to Applicant's SEQ ID NO: 13. (anti-CA IX monoclonal antibody; seq id no: 143). See sequence alignment available in Public PAIR under 'SCORE/SUPPL CONTENT' tab. With such a high degree of homology would be expected to bind (have cross reactivity) to the same antigens as to those which are instantly claimed. The reference teaches both polyclonal and monoclonal antibodies and hybridoma cell lines producing said monoclonal antibodies. Additionally, the reference teaches the use of antibodies as diagnostic reagents and kits comprising them. The term "vaccine" and "pharmaceutical composition" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of the antibodies. With respect to the product-by-process claims, e.g., claim 97, the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was

made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). Since Gudas et al teach antibodies with the same structure, eg., the antibodies would inherently possess at least one or more of the functional properties recited in claim 3.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/

Primary Examiner, Art Unit 1645

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